REMARKS

Claims 10 and 14-19, 21, 23, and 24 are pending in this application. Claims 1-9, 11-13, 20 and 22 were previously cancelled without prejudice to or disclaimer of the underlying subject matter. By way of the foregoing amendment, claim 19 is cancelled without prejudice to or disclaimer of the underlying subject matter. Claims 21, 23, and 24 have been amended. Support for the amendment can be found throughout the specification and claims as originally filed. No new matters enters by way of this amendment. Upon entry of the foregoing amendment, claims 14-18, 21, 23, and 24 will be pending.

I. Claim Objections

Claim 19 has been objected to under 37 C.F.R. 1.75 as allegedly "being a substantial duplicate of claim 14." Office Action at page 2. Applicants respectfully disagree, however, to facilitate prosecution, claim 19 has been cancelled without prejudice to or disclaimer of the underlying subject matter. As such, Applicants respectfully request the objection to claim 19 be withdrawn.

II. Claim Rejections – 35 U.S.C. § 101

Claims 10, 14-19, 21, 23, and 24 stand rejected under 35 U.S.C. § 101 "because the claimed invention lacks patentable utility." Office Action at page 3. Applicants respectfully traverse this rejection for at least the following reasons.

The Examiner bases this rejection on the allegation that "there is not convincing evidence that SEQ ID NO: 1, is in fact a transcription factor at all." *Id.* The Examiner

argues that "[i]t is uncertain if the fragment of SEQ ID NO: 1 that matches g642128 even encodes a transcription factor." *Id.* at pages 3-4. The Examiner concludes that "[w]ithout such knowledge, SEQ ID NO: 1 has no specific utility under 35 USC 101." *Id.* at page 4. Applicants disagree.

As the Examiner acknowledges, the specification clearly discloses that the nucleic acid molecules of the present invention encode a homeobox transcription factor or fragment thereof and provides evidence of significant homology to known homeobox transcription factors. *See, e.g.*, specification at page 31, lines 2-6, page 32, lines 6-11, page 56, line 11 through page 62, line 9, page 160, line 11 through page 232, line 3, Table A, and page 324, lines 19-23. The specification also explains the cellular role of the enzymes in transcription (*see, e.g.,* specification at page 3, line 10 through page 21, line 15). In addition, the specification also discloses the various families of transcription factors and their roles in different cellular processes. *See, e.g.,* specification at page 6, line 22 through page 21, line 15 and Table A. The specification describes the transcription factor or fragment thereof encoded by SEQ ID NO: 1 is a member of the homeobox transcription factor family of transcription factors. *See, e.g.*, specification at page32, lines 6-11, and page 233, Table A. One of ordinary skill in the art would recognize that the claimed nucleic acid molecules have utility, for example, to modify expression of genes in plant cells involved in, for example, regulation of cell-to-cell communication or development upon reading the present specification. It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). The instant specification discloses

many utilities that satisfy this requirement. These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The Examiner argues, however, that the claimed nucleic acid molecules lack utility apparently because the "sequence to which SEQ ID NO: 1 is aligned, g642128, in fact matches only 83.4% overall." Office Action at page 3. The Examiner alleges that "SEQ ID NO: 1 matches at base pair 54 to 320 of g642128, outside of any domains known to be associated with homeobox transcription factors" and further alleges that the this alignment is upstream of the encoding sequence of g642128. *Id.* However, the Examiner does not provide the sequence alignment.

The Examiner's asserts that SEQ ID NO: 1 aligns "outside of any domains known to be associated with homeobox transcription factors." *Id.* However, the NCBI website indicates that the coding sequence for gi642128 is located from nucleotides 24 through 650. Furthermore, the NCBI entry for gi642128 indicates that a MADS box is located at positions nt24-194, overlapping the region of alignment identified by the Examiner. This alignment encompasses the portion of gi642128 that is identified as at least overlapping the region encoding the MADS box portion of the homeotic gene PISTILLATA. *See, e.g.* National Center for Biotechnology Information, Genbank website for gi:642128 report under "Features" http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nucleotide&val=642128>.

The specification provides ample correlation between the claimed nucleic acid molecule and homeobox transcription factor proteins. Accordingly, the use of the claimed nucleic acid molecules to encode a homeobox transcription factor or fragment

thereof and corresponding uses associated with encoding such transcription factors satisfies the utility requirement of 35 U.S.C. § 101.

The "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met this part of the bargain – the present specification discloses nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, their use as promoter regions. *See, e.g.* Specification at page 16, line 12 through page 23, line 23. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit.

The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide <u>one</u> identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The Federal Circuit has recently provided guidance as to the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir, 2005). First, the Court indicated that the specification disclose "that an invention is useful to the public as disclosed in its current form." *Id.* at 1371. Second, the Court further noted that the specification "also show that

that claimed invention can be used to provide a well-defined and particular benefit." *Id.* Applicants have provided nucleic acid sequences which are shown in the specification to correlate to known genes. Such a correlation is sufficient to satisfy the utility standard. *Id.*

The present specification discloses specific and substantial uses for the nucleic acid molecules, including that they encode homeobox transcription factors (*see, e.g.,* specification at page 31, lines 2-6, page 32, lines 6-11, page 56, line 11 through page 62, line 9, page 160, line 11 through page 232, line 3, Table A, and page 324, lines 19-23) and to prepare constructs for plant transformation (*see, e.g.,* specification at page 100, line 19 through page 118, line 18).

The Examiner argues however that this utility is not specific or substantial, apparently because "one skilled in the art would have reason to doubt that sequence similarity alone would reasonably support the assertion that the biological activity of the claimed subject matter would be the same as that of the similar sequence." Office Action at page 4. More specifically, the Examiner argues that "it would have been well known that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases." *Id.* While the Examiner proceeds to analyze SEQ ID NO: 1 by citing several publications generally describing some unpredictability of the relationship between sequence and function in some proteins, the Examiner provides no support to show that SEQ ID NO: 1 does not encode a homeobox transcription factor as described by the specification. Such a utility is not vague or unknown. The asserted utility, to encode such a transcription factor or fragment thereof is a well-defined use that not any nucleic acid sequence can perform.

An examiner must accept a utility by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). "More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such as assertion." Federal Register 66(4):1096, Utility Guidelines (2001). "[A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996).

The specification provides ample correlation between the claimed nucleic acid molecule and homeobox transcription factor proteins. Accordingly, the use of the claimed nucleic acid molecules to encode a homeobox transcription factor or fragment thereof satisfies the utility requirement of 35 U.S.C. § 101.

The Examiner has not provided any evidence that would reasonably suggest that the claimed nucleic acids cannot be used for the aforementioned utilities, and therefore has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). In fact, the Examiner has provided no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. The Examiner "must do more than merely question operability - [she] must set forth factual reasons which would lead one skilled in the art to question the objective

truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. *Cf. In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

The Examiner further has not assessed the credibility of the presently asserted utilities. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* As previously stated, the Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation

to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not met this burden.

Applicants have disclosed several specific, substantial and credible utilities for the claimed nucleic acid molecules. Any one of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

III. Rejection Under 35 U.S.C. §112, first paragraph

Claims 10, 14-19, 21, 23, and 24 stand rejected under 35 USC § 112, 1st Paragraph because the claimed invention is allegedly not supported by either a specific and substantial asserted utility or a well established utility, and thus one of ordinary skill in the art would not know how to use the invention. This rejection is traversed for the reasons discussed above with regard to the 35 U.S.C. §101 rejection. As such, it is submitted that the specification enables one of skill in the art to use the invention in accordance with the asserted specific and substantial utilities discussed above. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

IV. Claim Rejections – 35 U.S.C. § 112, 2nd Paragraph, Indefiniteness

Claim 21, 23, and 24 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention." Office Action at page 5.

Claims 21 and 23 are rejected because the recitation of "found within a recombinant nucleic acid construct" is allegedly unclear. Similarly, claim 24 is rejected as the recitation of the phrase "said construct is found inserted into a plant genome" is also allegedly unclear.

Applicants respectfully point out that the claims are to be read in light of the specification. *See in re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert denied,* 112 S.Ct. 169 (1991). A person of ordinary skill in the art would understand the metes and bounds of claim 21, 23, and 24 read in light of the disclosure of the specification.

The Examiner alleges that claims 21, 23 and 24 are indefinite because the recitation of "found within" or "found inserted" is unclear Office Action at page 5. The claims are readily understandable by one of skill in the art when read in view of the specification. *See, e.g.*, Specification at page 100, line 19 through page 118 line 18. Although Applicants disagree, to facilitate prosecution, claims 21, 23, and 24 have been amended. Applicants therefore respectfully request reconsideration and withdrawal of the indefiniteness rejection of claim 35 under 35 U.S.C. § 112, second paragraph.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,

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